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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,318	09/26/2003	Robert G. Rani	N-32720A/USN	8415
1095	7590	01/11/2006	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			KHAIRA, NAVNEET K	
			ART UNIT	PAPER NUMBER
			3754	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,318

Applicant(s)

RANI, ROBERT G.

Examiner

Navneet Sonia Khaira

Art Unit

3754

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 25, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejection

ns under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-5, 7, 8, 10-14 and 16, 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Larkin et al (US 4,523,691).

Referring to claims 1- 2, 11, and 20 Larkin et al discloses a closure device for a flexible container containing a medical fluid comprising:

a pouch (col 1, line 6) having a port and at least a single edge such that the edge defines a reservoir within the pouch that is adapted to contain a fluid (col 1, lines 8-10);
and

a closure device adapted to fit the port and comprises (fig 4, col 1, line 53-54)

a base section (55, fig 14) having a top wall , a bottom wall, the base section adapted to fit the flexible container (fig 14, 46);

a mid-section (11) fig 1) connected to the top wall;

a support (15) connected to the base section and adapted for a user to grip the closure device;

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a cylindrical member extending through the base section (15, fig 4) and the support (14, fig 4), the cylindrical member (11, fig 1) having a first opening on the base (17, fig 1) section and a second opening (fig 4) between the support, the cylindrical member (11, fig 1) adapted to allow the fluid to flow to exit the flexible container (fig 7);

a first (26) seal blocking the cylindrical (11) and capable of being breached (col 4, lines 24-33);

a second seal (10,) wherein a portion of the cylindrical member between the first seal and the second seal defines a chamber (11, fig 1).

Referring to claims 3 and 12, Larkin et al further discloses the first seal (26, cap) covers the first opening (17).

Referring to claims 4 and 13, Larkin et al further discloses first seal comprises a weakened section (26, col 4, line 23).

Referring to claims 5 and 16, Larkin et al further discloses any material which can be injection molded and sealed can be employed as long as they are compatible with sealing to the port of an I.V. solution container in which case a seal made of peelable foil can be used if desired.

Referring to claim 7, cylindrical member (11, col 3, line 62-64) is adapted to receive a spike set.

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Referring to claims 8 and 18, the support has at least one wing (19, fig 12).

Referring to claim 10, Larkin et al further discloses the base (55, fig 11) section is boat-shaped.

Referring to claim 14, Larkin et al further discloses the closure device is made of a polymer material (col 4, lines 27-36).

Referring to claim 19, Larkin et al further discloses, the support (14) further comprises a raised surface as shown in fig 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 9, 15, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin et al (US 4,523,691).

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Referring to claims 6 and 17, it would have been obvious of ordinary skill in the art to modify the cylindrical member of Larkin et al to have desired a smaller diameter opening since the pouch contains medical fluid which is used in smaller portions. Larkin et al also discloses a cylindrical member (11) in fig 1 which seems to have a diameter between the range of about 0.5 mm to about 12 mm.

Referring to claim 9 and 15, it would have been obvious to one of ordinary skill in the art to assume a chamber is sterile after the closure device experiences a sterilization process (col 2, lines lines 19-21).

Citation of Related Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Larkin (US 4,547,900), Bujan (US 4,1187,893), and Gross (US 6, 439,429) and Ryan (3, 364,930) references also disclosed medical fluid dispenser closures with flexible pouches.

Response to Arguments

In response to applicant's arguments, the art previously applied still withstands the rejection. The supports used to grip the closure device that are not contained within the plastic bag can be identified as surface 15, which rests on the outer surface of the bag. Figure 7 shows the closure device which is in the manufacturing step, and once completed, device 43, 44 are removed. Therefore, to lift 26 as shown in fig 7, a surface

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would be necessary for the user to hold in order to lift 26. Hence since surface 15 is on the outer surface of the bag, the user would grip 15 while lifting 26.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navneet K. Khaira whose telephone number is 703-305-0860. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mar Y. Michael can be reached on 703-308-2087. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



01/09/05

Navneet Sonia Khaira
Examiner
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